Non-Confidential Summary of Safety and Effectiveness
Page 1 of 4
12-Jun-07

Omron Healthcare, Inc.
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Official Contact: Ranndy Kellogg – VP Marketing & Product Development

Proprietary or Trade Name: HBP T-105 Series Vital Signs monitor

Common/Usual Name: Monitor, Physiological, Patient (without arrhythmia detection or alarms)

Classification Name/Code: MWI – Monitor, Physiological, Patient (without arrhythmia detection or alarms)

Device: Models HBP T-105 and T-105S

Predicate Devices:
Colin – Press-Mate PM-2100 – K022537
Omron – HEM 907 – K001848
Omron – HEM 757 – K001670
Nellcor – N595 – K012891
Nellcor – Oximax – K052186
Masimo – RAD 5 – K033296
Masimo – LNCS – K041815

Device Description:

The Omron HBP T-105 Series is a modification of the Colin Press-Mate PM-2100 and is intended to monitor a single patient's vital signs. The device is capable of monitoring:

- Pulse rate (via oximetry data);
- Non-invasive pressure (systolic, diastolic and mean oscillometric (NIBP);
- Temperature; and
- Blood Oxygen Saturation (SpO_2 via finger oximeter)

Indications for Use:

The T-105 Series Vital Signs Monitor is intended to monitor a single patient's vital signs in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel who will determine when use of this device is indicated, based upon their professional assessment of the patient's medical condition. The patient populations include adult, pediatric and neonatal. The device is capable of monitoring:

Non-Confidential Summary of Safety and Effectiveness
Page 2 of 4
12-Jun-07

- Pulse rate (via oximetry data)
- Non-invasive pressure (systolic, diastolic and mean oscillometric (NIBP)
- Temperature
- Blood Oxygen Saturation (SpO_2 via finger oximeter)

This device is intended for use by qualified healthcare personnel trained in its use.

Patient Population: Adult, pediatric, neonate

Environment of Use: Hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel who will determine when use of this device is indicated, based upon their professional assessment of the patient's medical condition.

Contraindications: None

Summary of substantial equivalence

Specification	**Predicate** **PM2100 – K022537**	**New Models** **HBP-T105 T-105S**
Power source	Battery (Tin acid) or AC	Battery(Lead-acid) or AC adapter
Power range	AC : 100-120V,220-240V,50/60Hz Battery6V 5Ah	AC : 100-115V,220-240V,50/60Hz Battery12V 3.2Ah
Display	Monocolor LCD and LED	LED
Operating conditions	0 to 50 °C, 30 to 85 %RH	0 to 40 °C, 30 to 85 %RH
Storage conditions	-20 to 70 °C, 30 to 85 %RH	-20 to 60 °C, 10 to 95 %RH
Dimensions (mm)	240 (W) × 250 (D) × 238 (H) mm	239 (W) × 239 (D) × 150 (H) mm
Weight (without batteries)	7.5 lbs	7.7 lbs
BP module	M2600	M3600
Measurement method	Oscillometric method	same as predicate device
Patient target	Adult/Pediatric/Neonatal	same as predicate device
Measurement range	Pressure: 0 to 300 mmHg Pulse rate: 40 to 240 beats/min.	Pressure: 0 to 299 mmHg Pulse rate: 40 to 240 beats/min.
Pressure sensor	Semiconductor pressure sensor	same as predicate device
Air Control Valve	Electromagnetic solenoid	Omron HEM907 - K001848
Applicable cuff	Regular sized cuff	Omron HEM907 - K001848

Non-Confidential Summary of Safety and Effectiveness
Page 3 of 4
12-Jun-07

Specification	Predicate PM2100 – K022537	New Models HBP-T-105 / T-105S
Accuracy of pressure indicator	Within ±3 mmHg or 1 % of reading	same as predicate device
Accuracy of pulse rate	Within ±2 beats/min or ±2% of reading	same as predicate device
Inflation method	DC Rolling diaphragm pump	same as predicate device
Deflation method	Dynamic linear deflation	same as predicate device
Quick measurement function of Blood Pressure	No algorithm	Omron algorithm HEM-757 - K001670
SpO_2 Measurement method	2 wave length pulse wave type	same as predicate device
SpO_2 display range	0 to 100 %	same as predicate device
SpO_2 module	Nellcor NELL-3(MP-506)	Nellcor NELL-1 N-595 - K012891 same technology as NELL-1. Masimo MS-11 RAD-5 - K033296 same technology as MS-11. User can select which one
Accuracy of SpO_2	D-25 disposable sensor SpO_2:70-100% ±2% other ranges unspecified N-25 disposable sensor SpO_2:70-95% ±2% other ranges unspecified	Nellcor - Same as predicate OXIMAX Sensors - K052186 Add option of - Masimo SpO_2:70-100% ±2% LNCS sensors - K041815
Pulse rate display range	20 - 250 beats/min	Nellcor -same as predicate device Masimo -25 - 240 beats/min
Accuracy of pulse rate	Within ±3 beats/min	Nellcor - same as predicate device Masimo - Within ±3 beats/min
Temperature Measurement method	TURBO TEMP electronic predictive thermometer	same as predicate device
TEMP display range	Predictive mode: 35.6 - 41.1°C / 96-106°F Monitor mode: 26.7 - 41.1° / 80 - 106°F	same as predicate device
Accuracy of TEMP	±0.1°C / ±0.2°F	same as predicate device
Scale	Selectable from °C to °F	same as predicate device
Shock protection	Type BF(Defibrillator protected)	same as predicate device

Non-Confidential Summary of Safety and Effectiveness

12-Jun-07

Differences Between Other Legally Marketed Predicate Devices

The Model HBP T-105 Series is viewed as substantially equivalent to the following predicate device – Colin Press-Mate PM-2100 – K022537.

The difference between the Model T-105 and T-105S is that the T-105S model does not have the ability to set the time interval of the BP measurement. The T-105S model BP is done on an as needed / manual activation basis. All other features, specifications, etc. are otherwise identical.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2007

Omron Healthcare, Inc.
c/o Mr. Paul Dryden, ProMedic, Inc.
3460 Pointe Creek Court # 102
Bonita Springs, FL 34134-2015

Re: K071645
HBP-105 and T-105S
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: June 12, 2007
Received: June 15, 2007

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K071645 (To be assigned)

Device Name: HBP T-105 and T-105S

Indications for Use:

The T-105 Series Vital Signs Monitor is intended to monitor a single patient's vital signs in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel who will determine when use of this device is indicated, based upon their professional assessment of the patient's medical condition. The patient populations include adult, pediatric and neonatal. The device is capable of monitoring:

- Pulse rate (via oximetry data)
- Non-invasive pressure (systolic, diastolic and mean oscillometric (NIBP)
- Temperature
- Blood Oxygen Saturation (SpO_2 via finger oximeter)

This device is intended for use by qualified healthcare personnel trained in its use.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ambili Bvan for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071645